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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,027	11/14/2003	Romano Mongiorgi	2503-1074	7509
466	7590	12/15/2005	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			FLOOD, MICHELE C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,027	MONGIORGI, ROMANO	
	Examiner	Art Unit	
	Michele Flood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election with traverse of Group II, Claims 6 and 15-20, and the provisional election of the species, *Rheum*, in the reply filed on November 21, 2005 is acknowledged. The traversal is on the ground that the examination of all the claims in their full scope fails to place a burden on the Patent Office. This is not found persuasive for all of the reasons set forth clearly in the previous Office action. However, the restriction requirement for election of species has been withdrawn as the Office finds that the search for each of the claim-designated active ingredients comprising an extract having at least one compound selected from the group consisting of *Rheum* genus and *Spinacia oleracea* L. compounds fails to place a burden on the Patent Office.

The requirement is still deemed proper and is therefore made FINAL.

Claims 6 and 15-20 are under examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6, 15, 16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gortner et al. (UU1, Journal of Nutrition (1946), 32: 121-131. Some effects of dietary oxalate on the teeth of white rats).

Applicant claims a method for treating dentinal hypersensitivity in a patient comprising administering an effective amount of an active ingredient to said patient, wherein the active ingredient comprises an extract having at least one compound selected from the group consisting of *Rheum* genus and *Spinacia oleracea* L. compounds. Applicant further claims the method as claimed in claim 6, wherein the compounds are in the form of a liquid, soft or dry extracts; and, wherein the active ingredient is administered in the form of a paste, gel, mouthwash, spray solution, sweets, chewing gum, solution or powder, and wherein the active ingredient is present in an amount of 0.5 to 50% by weight.

Gortner teaches a method of administering an effective amount of ingredient selected from the claim-designated plant extracts. For instance, Gortner teaches a methods of administering effective amounts of either spinach (*Spinacia olerarea* L.) leaf extract and animal feed or rhubarb juice (*Rheum* genus) to rats bearing acid eroded teeth wherein destruction of tooth occurred formed a hard deposit on the molars of the rats. For example, on page 126, line 5 to page 127, line 4, Gortner teaches that the administration of 8% of dry spinach extract combined with a ground dog feed diet to rats feed phosphoric acid beverage forms a hard deposit on the molars of the rats. Gortner father teaches, "Similar results have been obtained by allowing rats to drink rhubarb juice (extract and solution) for 1 week", on page 127, lines 24-26. See page 127, lines 13-28, in its entirety.

The Office notes that Gortner does not expressly teach the referenced method comprising the administration of effective amounts of a spinach extract in combination

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with an animal feed diet or the referenced method comprising the administration of effective amounts of rhubarb juice to the test animals as methods for treating dental hypersensitivity in a patient. However, the methods taught by Gortner comprise the administration of one and the same ingredient, namely either extracts of either spinach or rhubarb to a patient, and wherein in the percentage amount for the administration of the one and the same ingredient is the same or essentially the same as instantly disclosed by Applicant as having the beneficial functional effect to provide a method for treating hypersensitivity in a patient. Therefore, the instantly claimed beneficial effect is considered to be inherent to the method of treatment taught by Gortner.

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 18 and 19 are rejected under 35 U.S.C. 102(b) as anticipated by Gortner et al. (UU1) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gortner et al. (UU1), Hack et al. (A*) and Pashley et al. (B*); and, as evidence readily admitted by Applicant.

Gortner teaches a method of administering an effective amount of ingredient selected from the claim-designated plant extracts. For instance, Gortner teaches a methods of administering effective amounts of either spinach (*Spinacia oleracea* L.) leaf extract and animal feed or rhubarb juice (*Rheum* genus) to rats bearing acid eroded teeth wherein destruction of tooth occurred formed a hard deposit on the molars of the rats. For example, on page 126, line 5 to page 127, line 4, Gortner teaches that the administration of 8% of dry spinach extract combined with a ground dog feed diet to rats feed phosphoric acid beverage forms a hard deposit on the molars of the rats. Gortner further teaches, "Similar results have been obtained by allowing rats to drink rhubarb juice (extract and solution) for 1 week", on page 127, lines 24-26. See page 127, lines 13-28, in its entirety.

The claims are drawn to a method for treating dentinal hypersensitivity in a patient comprising administering an effective amount of an active ingredient to said patient, wherein the active ingredient comprises an extract having at least one compound selected from the group consisting of *Rheum* genus and *Spinacia oleracea* L. compounds.

The teachings of Gortner are set forth above. Although Gortner does not expressly teach the referenced methods for the administration of either a dry spinach extract or an extract of rhubarb, that is rhubarb juice, to rats bearing acid eroded teeth as methods for treating dentinal hypersensitivity in a patient, the methods taught by Gortner are deemed to inherently comprise the claim-designated method of treatment, since Gortner teaches the administration of the same ingredients and the same

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amounts of the same ingredients to a patient in need thereof; and, hence, it is considered to anticipate the claimed subject matter considering the ingredients, the amounts of the ingredients, and the experimental parameters for the administration of the ingredients are one and the same as instantly claimed by Applicant.

In the alternative, even if the claimed method of treatment is not identical to the referenced method with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced method is likely to inherently possess the same characteristics of the claimed method particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed method for treating dental hypersensitivity in a patient comprising the administration of the claim-designated ingredients would have been obvious to those of ordinary skill in the art within the meaning of USC 103. For instance, even if the claimed method is not clearly anticipated, it would have been obvious to one of ordinary skill in the art to administer an effective amount of either of the active ingredients compositions comprising an extract having at least one compound selected from the group consisting of spinach or rhubarb to a patient taught used in the methods of treatment taught by Gortner to provide the instantly claimed method of treatment because at the time the invention was made it was known in the art of medicinal dentistry that dentinal hypersensitivity is a condition caused by exposure of the dentine to the environment and that a factor inducing dentinal hypersensitivity includes erosion of tooth enamel and dentin by the ingestion of solutions of various food acids, as readily admitted by Applicant on page 2, lines 5-9 of the present specification,

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and on page 7, line 24 to page 8, line 13 of Applicant's "Remarks" filed on February 28, 2005. Moreover, Gortner teaches that when oxalate-containing compositions comprising oxalic acids or its sodium salt was present in an animal's diet or drink, decalcification or erosion of tooth enamel by food acids (citric, lactic, phosphoric or sulfuric acids) diminished or disappeared. Furthermore, Gortner further teaches that oxalate-containing foods, such as spinach and rhubarb, when incorporated into the diet of an animal provided a protective film on the molars of the rats. It also would have been obvious to one of ordinary skill in the art would have been motivated to administer an effective amount of either of the plant extract compositions taught by Gortner to a patient to provide the instantly claimed method of treatment because at the time the invention was made the use of oxalates in the treatment of dentinal hypersensitivity was well known in the art of medicinal dentistry, as readily admitted by Applicant on page 3, lines 12-20 of the present specification; and, as evidenced by the teachings of Hack and Pashley. One of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to employ the methods taught by Gortner to provide a method for treating dentinal hypersensitivity in a patient comprising the administration of effective amounts of the claim-designated ingredients because at the time the invention was made it was well known in the art that the onset of dentinal hypersensitivity is induced by the erosion of enamel and dentin by acid containing food products, as evidenced by the teachings of Gortner wherein Gortner teaches that habitual ingestion of acids by the test animals lead to tooth erosion; and, since Gortner teaches that the administration of effective amounts of the instantly claimed ingredients

comprising an effective amount of oxalate provided a protective layer over the surface of the test subjects having exposed enamel; and, since Hack and Pashley teach that the administration of effective amounts a composition comprising oxalate to a patient in need thereof is useful in methods for reducing tooth or dentinal hypersensitivity.

The United States Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicant's claimed method differs and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to Applicant.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Claims 6 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gortner et al. (UU1), Hack et al. (A*) and Pashley et al. (B*); and, as evidence readily admitted by Applicant, and in further view of McCay et al. (WW1) and Kasidas et al. (V).

Applicant's claimed invention of Claims 6, 18 and 19 was set forth above. Applicant further claims the method as claimed in claim 6, wherein the active ingredients comprise *Rheum* genus and *Spinacia oleracea* L.

The obvious teachings of Gortner are set forth above. The obvious teachings of Gortner do not teach a method for treating dentinal hypersensitivity comprising, wherein

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the active ingredients comprise *Rheum* genus and *Spinacia oleracea* L. However, it would have been obvious to one of ordinary skill in the art to provide the instantly claimed method of treatment by combining the active ingredients obtained from both rhubarb and spinach to provide the instantly claimed invention because at the time the invention was known it was known in the art that oxalate was present in rhubarb and spinach, as evidenced by the teachings of McCay and Kasidas. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to add the instantly ingredients to provide the claimed method of treating dentinal hypersensitivity because Gortner teaches, "The presence of oxalic acid or its Na salt in the rats food or drink prevented or diminished the decalcification of teeth which accompanies the ingestion of phosphoric and citric acid solutions"; McCay teaches that sodium oxalate ingested with food deposits patches on the teeth and that the prevention of molar teeth by acid beverages can be effected by the administration of oxalic acid dissolved in an acid beverage, such as rhubarb juice combined with equal parts of lemon juice; and Kasidas teaches that spinach and rhubarb comprise high levels of oxalate. Thus, the claimed invention is no more than the combining of active ingredients known in the art to produce protective film formation on teeth, wherein the active ingredients are compounds, namely oxalate compounds and wherein the oxalate compounds were known to be extracted from the claim-designated plants of rhubarb (genus *Rheum*) and spinach (*Spinacia oleracea* L.).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claim 6 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gortner et al. (UU1) in view of Ohkawa (U).

Applicant's claimed invention of Claims 6, 15 and 18-20 was set forth above. Applicant further claims the method of claim 6, wherein the compounds are obtained by hydroalcoholic extraction from rhubarb roots; and wherein the compounds are obtained by hydroalcoholic extraction from *Spinacia oleracea* L. leaves.

The obvious teachings of Gortner are set forth above. The obvious teachings of Gortner teaches the instantly claimed invention except for wherein the compounds are obtained by hydroalcoholic extraction from rhubarb roots; and wherein the compounds are obtained by hydroalcoholic extraction from rhubarb roots. However, it would have been obvious to one of ordinary skill in the art to modify the obvious method of treating dentinal hypersensitivity in a patient in need thereof by taught by Gortner by replacing the spinach extract and rhubarb juice with the instantly claimed ingredients because at the time the invention was made it was known in the art that hydroalcoholic extracts of either rhubarb roots or *Spinacia oleracea* L. leaves contained active ingredient compounds, which were beneficial in the making of compositions that were useful in methods of treating dentinal hypersensitivity in a patient. For instance, Ohkawa teaches a method for determining the concentration of oxalic acid and recovering amounts of

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oxalic acid in food products, such as spinach and beverages, comprising extracting a sample of the food product with water to obtain soluble oxalic acid or 2N hydrochloric acid, evaporating the sample to dryness and recovering oxalic acid contained therein a residue with a methanol solution. Thus, while Gortner teaches that the administration of either oxalate-containing dry spinach extract or oxalate-containing rhubarb juice extract to rats bearing acid-eroded teeth provided a protective effect against tooth destruction by acid food products, it would have been obvious to one of ordinary skill in the art to replace the spinach leaf extract and/or rhubarb beverage with a hydroalcoholic extract of either of the instantly claimed ingredients because Ohkawa teaches that oxalate or oxalic acid can be extracted from food products by hydroalcoholic solvents. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to replace the dry spinach leaf extract and the rhubarb juice extract with a hydroalcoholic extract of either of the instantly claimed ingredients to provide the instantly claimed invention because Ohkawa teaches that the recovery of oxalate from oxalate containing foods can be achieved by hydroalcoholic solvent extraction. Thus, the claimed invention is no more than the combining of active ingredients known in the art to produce protective film formation on teeth, wherein the active ingredients are compounds, namely oxalate compounds and wherein the oxalate compounds were known to be extracted from the claim-designated plants of rhubarb (genus *Rheum*) and spinach (*Spinacia oleracea* L.).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
December 10, 2005